Remarks

Claim 13 has been cancelled without prejudice or disclaimer, and with the understanding that Applicants may file a continuation application with claims directed to the cancelled subject matter. Claim 1 has been amended to correct a typographical error.

1. Rejection under 35 U.S.C. 112, first paragraph

Claims 13 and 14 are rejected for allegedly lacking enablement.

While Applicants do not agree with this position taken by the Examiner, Applicants have nevertheless cancelled claim 13 without prejudice or disclaimer to expedite prosecution of the subject application. Therefore, Applicants submit that this rejection of claim 13 has been effectively mooted.

Regarding claim 14, directed to a pharmaceutical composition, Applicants are of the opinion that the Examiner has failed to assert a proper rejection of the pharmaceutical composition claim as lacking enablement. A review of the specification reveals that the claimed compounds, which the Examiner has determined as patentable, are indicated as being of value in treating hyperlipidaemia (see, *inter alia*, paragraph [0005] in the published application). As confirmation, see also the two documents that Applicants have submitted for the Examiner's review that confirm the use of IBAT inhibitors for the treatment of hyperlipidaemia. The first document (an English-language abstract of Nippon Rinsho. 2002, 60(1), 130-6) states that IBAT inhibitors "may be used alone or in combination with HMG-CoA reductase inhibitors in the treatment of hypercholesterolemia." The second document indicates that AstraZeneca took several IBAT inhibitors into clinical trials for treating dyslipidaemia.

The specification also teaches routes of administration of the claimed compounds (see, inter alia, paragraph [0116] in the published application), dose ranges (see, inter alia, paragraph [0118] in the published application) and the presence of excipients and/or carriers (see, inter alia, paragraph [0117] in the published application). Accordingly, Applicants do not understand the basis for this rejection by the Examiner and respectfully request that the Examiner identify the regulation or case law that provides support for the rejection.

If the Examiner is perhaps reading into the composition claim a use limitation of of the compounds in treating a disease state, Applicants submit that this interpretation is improper, as the pharmaceutical composition claim simply indicates that the excipient components in the composition are pharmaceutically acceptable and excluding those components that are pharmaceutically unacceptable. A person of ordinary skill in this art would clearly be able to differentiate between these two classes of excipient components.

2. Rejection under 35 U.S.C. 112, second paragraph

Claim 13 is rejected for allegedly being indefinite. The Examiner asserts that a method of inhibiting IBAT is indefinite because it allegedly is not known which diseases are capable of being responsive to IBAT inhibition.

While Applicants do not agree with this position taken by the Examiner, Applicants have nevertheless cancelled claim 13 without prejudice or disclaimer to expedite prosecution of the subject application. Therefore, Applicants submit that this rejection of claim 13 has been effectively mooted.

The Examiner has also rejected claims 1, 4, 6, 7, 9, 13 and 14 as allegedly being indefinite because the Examiner asserts that it is not known what is meant by the moiety methylS(O)a. The Examiner suggests that Applicants intended methylS(O)a.

Applicants have amended claim 1 as suggested by the Examiner. Claims 4, 6, 9 and 14 depend from claim 1 and therefore incorporate this amendment. Claim 13 has been cancelled without prejudice or disclaimer. Claim 7 does not recite this particular moiety. Accordingly, Applicants request that this rejection be withdrawn.

3. Obviousness-Type Double Patenting Rejections

A. 10/502,355

Claims 13 and 14 are provisionally rejected as allegedly unpatentable over claims 1, 2, 6, 8, 10, 13, 14 and 18-20 of copending Application No. 10/502,355.

Applicants do not agree with this rejection, but have cancelled claim 13 without prejudice

or disclaimer, thus effectively mooting the rejection as it pertains to claim 13. While Applicants also do not agree with the Examiner's rejection of claim 14, Applicants are filing herewith a terminal disclaimer of the subject application over copending Application No. 10/502,355 in an effort to expedite prosecution.

B. 10/488,540

Claims 1, 4-9, 13 and 14 are provisionally rejected as allegedly unpatentable over claims 1-12, 17 and 18 of copending Application No. 10/488,540.

Applicants do not agree with this rejection, but have cancelled claim 13 without prejudice or disclaimer, thus effectively mooting the rejection as it pertains to claim 13. While Applicants also do not agree with the Examiner's rejection of claims, 1, 4-9 and 14, Applicants are filing herewith a terminal disclaimer of the subject application over copending Application No. 10/488,540 in an effort to expedite prosecution.

C. 10/451,262

Claims 1, 4-9, 13 and 14 are provisionally rejected as allegedly unpatentable over claims 1-16, 20, 21 and 29 of copending Application No. 10/451,262.

Applicants do not agree with this rejection, but have cancelled claim 13 without prejudice or disclaimer, thus effectively mooting the rejection as it pertains to claim 13. While Applicants also do not agree with the Examiner's rejection of claims, 1, 4-9 and 14, Applicants are filing herewith a terminal disclaimer of the subject application over copending Application No. 10/451,262 in an effort to expedite prosecution.

4. Conclusion

The foregoing amendments and remarks are being made to place the application in a condition for allowance. Applicant respectfully requests reconsideration and the timely allowance of the pending claims. Should the Examiner find that an interview would be helpful to further prosecution of this application, she is invited to telephone the undersigned at her

convenience.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application, including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or to credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

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